

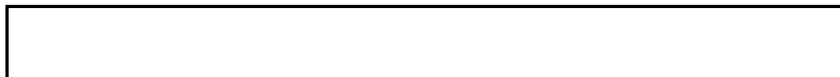
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13 DEC 1978

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MEMORANDUM FOR: Director of Central Intelligence

FROM:



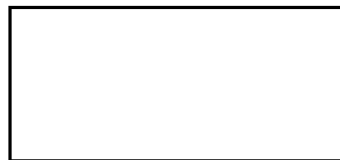
STATINTL

SUBJECT: Protection of Human Subjects in Research Undertaken  
or Sponsored by the Intelligence Community

1. Attached are memoranda for the National Foreign Intelligence Board (NFIB), Department of Health, Education and Welfare (DHEW), and the National Commission for the Protection of Human Subjects of Bio-medical and Behavioral Research with a proposed DCID which provides guidelines for human subject research within the Intelligence Community (Attachments 1, 2, and 3).

2. The research elements of the Intelligence Community have the dual responsibility of protecting human subjects in research as well as intelligence sources and methods. A potential exists for the two to come into conflict. The proposed DCID minimizes that potential by establishing and publishing, within the Community, guidelines to be followed. The DCID will implement section 5.d. of E.O. 11905 and will be in accord with Director Colby's statement of 1 August 1975 regarding guidelines on use of human subjects in research (Attachment 4).

3. I recommend your signature on the proposed memoranda which provide background information and transmit the proposed directive to the NFIB, DHEW, and the National Commission for their comments and where applicable, concurrence.



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## Attachments:

- 1 - Proposed Letter to NFIB
- 2 - Proposed Letter to DHEW
- 3 - Proposed Letter to National Commission
- 4 - Director Colby's Statement dtd 1 Aug 75

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Approved For Release 2004/08/25 : CIA-RDP79M00467A000300040009-6

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NATIONAL FOREIGN INTELLIGENCE BOARD

Executive Registry

76-438911

16 DEC 1976

MEMORANDUM FOR THE NATIONAL FOREIGN INTELLIGENCE BOARD

FROM: George Bush  
Chairman

SUBJECT: Protection of Human Subjects in Research Undertaken or  
Sponsored by the Intelligence Community

1. Attached is a proposed DCID which states the concern of the Intelligence Community for the protection of human subjects in research projects and provides guidelines to assure the necessary protection.
2. The proposed directive will implement section 5.d. of Executive Order 11905 and demonstrate responsiveness to recommendations of Congressional committees that the Department of Health, Education and Welfare (DHEW) Guidelines (PL 93-348) be followed in conducting research which requires human subjects. Though PL 93-348, which applies to DHEW, sets out the minimum standard which can be considered permissible for Intelligence Community research activities, it does not address several issues pertinent to intelligence. That legislation also established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Section 5.d., E.O. 11905 states that the foreign intelligence agencies are to comply with the guidelines of the National Commission in conducting human (drug) research.
3. None of these authorities addresses the generic problem that arises when the element of security classification is introduced. The Intelligence Community has the dual responsibility of protecting human subjects in its research as well as protecting intelligence sources and methods. Because both responsibilities must be met, the potential exists for the two to come in conflict. The key elements of the DHEW Guidelines call for: (a) review of the proposed research by autonomous bodies (Institutional Review Boards) and (b) informed consent procedures which provide a thorough explanation of the procedures and attendant risks or benefits so that the subject can make a reasoned decision

whether to participate. These requirements for disclosure may be in conflict with traditional security practices. The proposed directive provides guidance to correct that circumstance.

4. When promulgated, this recommended policy would assist in the protection of human rights; be responsive to recommendations of Presidential and Congressional investigatory commissions; and be in consonance with guidance issued by currently authorized commissions whose principal concern is the protection of human life, rights and dignity.

5. Please review the proposed DCID and send your comment and/or concurrence to the NFIB Secretariat by 15 January 1977. This item will not be placed on the NFIB agenda unless so requested by a Member.

**/s/ George Bush**

George Bush

Attachment:  
Proposed DCID

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Executive Registry

76.4389/2

NATIONAL FOREIGN INTELLIGENCE BOARD

16 DEC 1976

MEMORANDUM FOR: Dr. Donald T. Chalkley  
Director, Office for the Protection  
from Research Risks  
The National Institute of Health

FROM: George Bush  
Chairman

SUBJECT: Protection of Human Subjects in Research  
Undertaken or Sponsored by the Intelligence  
Community

1. Attached is a proposed DCID which states the concern of the Intelligence Community for the protection of human subjects in research projects and provides guidelines to assure the necessary protection.

2. The proposed directive will implement section 5.d. of Executive Order 11905 and demonstrate responsiveness to recommendations of Congressional committees that the Department of Health, Education and Welfare (DHEW) Guidelines (PL 93-348) be followed in conducting research which requires human subjects. Though PL 93-348, which applies to DHEW, sets out the minimum standard which can be considered permissible for Intelligence Community research activities, it does not address several issues pertinent to intelligence. That legislation also established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Section 5.d., E.O. 11905 states that the foreign intelligence agencies are to comply with the guidelines of the National Commission in conducting human (drug) research.

3. None of these authorities addresses the generic problem that arises when the element of security classification is introduced. The Intelligence Community has the dual responsibility of protecting human subjects in its research as well as protecting intelligence sources

and methods. Because both responsibilities must be met, the potential exists for the two to come in conflict. The key elements of the DHEW Guidelines call for: (a) review of the proposed research by autonomous bodies (Institutional Review Boards) and (b) informed consent procedures which provide a thorough explanation of the procedures and attendant risks or benefits so that the subject can make a reasoned decision whether to participate. These requirements for disclosure may be in conflict with traditional security practices. The proposed directive provides guidance to correct that circumstance.

4. When promulgated, this recommended policy would assist in the protection of human rights; be responsive to recommendations of Presidential and Congressional investigatory commissions; and be in consonance with guidance issued by currently authorized commissions whose principal concern is the protection of human life, rights and dignity.

5. The proposed DCID has been forwarded for your information. Your comments or suggestions regarding the directive are welcomed. In the event you desire any additional background information regarding this directive, please call [redacted] (Telephone: [redacted] of the Intelligence Community Staff. To coincide with the NFIB due date, receipt of any remarks by 15 January 1977 would be most appreciated.

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/s/ George Bush

George Bush

Attachment:  
Proposed DCID

Executive Registry

76-4389/B

NATIONAL FOREIGN INTELLIGENCE BOARD

16 DEC 1976

MEMORANDUM FOR: Dr. Kenneth J. Ryan  
Chairman, National Commission for the  
Protection of Human Subjects of  
Biomedical and Behavioral Research

FROM: George Bush  
Chairman

SUBJECT: Protection of Human Subjects in Research  
Undertaken or Sponsored by the Intelligence  
Community

1. Attached is a proposed DCID which states the concern of the Intelligence Community for the protection of human subjects in research projects and provides guidelines to assure the necessary protection.

2. The proposed directive will implement section 5.d. of Executive Order 11905 and demonstrate responsiveness to recommendations of Congressional committees that the Department of Health, Education and Welfare (DHEW) Guidelines (PL 93-348) be followed in conducting research which requires human subjects. Though PL 93-348, which applies to DHEW, sets out the minimum standard which can be considered permissible for Intelligence Community research activities, it does not address several issues pertinent to intelligence. That legislation also established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Section 5.d., E.O. 11905 states that the foreign intelligence agencies are to comply with the guidelines of the National Commission in conducting human (drug) research.

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**7:7 George Bush**

George Bush

Attachment:  
Proposed DCID

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75-3368/A

ORD 2873-75

1 AUG 1975

Charles U. Lowe, M.D.  
Executive Director  
National Commission for the Protection  
of Human Subjects of Biomedical and  
Behavioral Research  
Westwood Building, Room 125  
5333 Westbard Avenue  
Bethesda, Maryland 20916

Dear Dr. Lowe:

The quotation in your letter taken from page 228 of the  
Report to the President by the Commission on CIA Activities  
Within the United States (June 1975) is correct.

Without exception, the following paragraph is inserted  
into experimental research contracts involving human subjects:

"PROTECTION OF HUMAN SUBJECTS:

In the performance of this contract, the contractor will assume responsibility for adhering to established and accepted professional, ethical, and legal practices in the use of human subjects for research purposes. This will include the maintenance of medical confidentiality of the individual subjects' records and the maintenance of anonymity in data forwarded to the Sponsor."

The protection of human rights is a matter of serious concern to the Central Intelligence Agency. Research proposals dealing with human subjects are not acted upon until the submitting institution or contractor provides evidence that the proposal has been reviewed and approved by the submitting institutions' "Ethics Committee". In May 1974, a

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W. Colby B. Lowe  
30 July 1975  
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group of CIA officials met with Dr. Stephen Hatchett and Dr. Donald Chalkley of DHEW to discuss this matter and to assure ourselves that the Agency had been and would continue to be in compliance with the then evolving Federal Guidelines and legislation.

The procedures thus far have proved to be totally satisfactory. I would appreciate it if you would be willing to provide consultation to the Agency on this most important issue should it prove necessary in the future.

Thank you for your interest and concern.

W. E. Colby

William E. Colby  
Director

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(30 July 1975)

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